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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/714,081	11/16/2000	Joaquin Villalobos	CRD-726	5133

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EXAMINER
MILLER, CHERYL L

ART UNIT	PAPER NUMBER
3738	

DATE MAILED: 05/13/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/714,081	VILLALOBOS ET AL.	
	Examiner	Art Unit	
	Cheryl L. Miller	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 November 2000* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *16 November 2000* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *3* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Specification

1. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

Line 1 of the abstract recites the phrase "In accordance with the present invention", which is improper language and should be deleted.

Drawings

1. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "41" has been used to designate both flanges (pg.17, line 19) and interior surface (pg.13, line 10). Other similar errors occur throughout the specification. Reference characters "1 and 2" have been used to designate both iliac arteries (pg.19, line 25) and femoral arteries (pg.19, line 12). It is suggested to change "femoral arteries" to --iliac arteries-- on page 19, line 12. Reference character "300" has been used to designate both infrarenal neck (fig.19, 20; pg.19, line 22) and delivery apparatus (fig.23, 25; pg.18, lines 3, 5, 10). Reference characters "300" (figs.19, 20; pg.19, line 22) and "3" (figs.16-18; pg.19, line 7) have both been used to designate infrarenal neck. Reference character "132" has been used to designate both delivery apparatus (figs.17, 18; pg.19, lines 11-12) and outer sheath (fig.15; pg.17, lines 10, 14). Reference characters 82 and 84 have been used to designate different parts in figure 8, than in figure 9. It is suggested to delete 82 and 84 from figure 8. Reference characters "10" and "12" and "40" and "80" have all been used to designate stent. It is confusing to the examiner, which stent applicant is referring to throughout the specification. Phrase "precursor stent" should be used each time (10) is mentioned throughout the specification. Phrase "member" should be used each time (12) is mentioned

throughout the specification. Phrase "stent" should be used each time (40) is mentioned throughout the specification. Phrase "stent-graft" should be used each time (80) is mentioned throughout the specification. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference sign(s) not mentioned in the description: 43A, 43B (figs.4, 15) and 72 (fig.6). A proposed drawing correction, corrected drawings, or amendment to the specification to add the reference sign(s) in the description, are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance. It is suggested to assign reference numeral 43A to interior surface and reference numeral 43B to exterior surface on page 13, line 10.

Claim Objections

3. Claim 12 is objected to because of the following informalities: A grammar error is present in line 1. "The apparatus according to claim 4 said" should be changed to recite --The apparatus according to claim 4 wherein said--. Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 6, 9, and 11 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The applicant

claims a shape (either I or T shaped) for the grooves and flanges. These limitations were not discloses in the specification.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. Claim 1 recites the limitation "said member" in lines 8 and 9. There is insufficient antecedent basis for this limitation in the claim. It is unclear whether applicant is referring to "elongated tubular member" or "removable member". Claims 2-3 depend upon claim 1 and inherit problems associated with the parent claim.

9. Claim 2 recites the limitation "said inner member" in line 2. There is insufficient antecedent basis for this limitation in the claim.

10. Claim 3 recites the limitation "said outer shaft" in line 2. There is insufficient antecedent basis for this limitation in the claim. It is suggested to change "said outer shaft" to recite --said outer sheath--.

11. Claim 4 recites the limitations "said self-expanding member" and "said member" in lines 12, 8, 9, 16, and 17. There is insufficient antecedent basis for these limitations in the claim. It is suggested to change "said self-expanding member" on line 12, to recite --said self-expanding stent--. It is unclear what is meant by "said member". It is unclear whether applicant is referring to "elongated tubular member" or "removable member". Claims 5-13 depend upon claim 4 and inherit problems associated with the parent claim.

12. Claim 8 recites the limitations "said member" and "said precursor stent" in line 2. There is insufficient antecedent basis for these limitations in the claim.

13. Claim 10 recites the limitations "The precursor stent" and "said expandable member" in lines 1 and 2 respectively. There is insufficient antecedent basis for these limitations in the claim.

14. Claim 11 recites the limitation "The precursor stent" in line 1. There is insufficient antecedent basis for this limitation in the claim.

15. Claim 12 recites the limitation "said inner member" in line 2. There is insufficient antecedent basis for this limitation in the claim.

16. Claim 13 recites the limitation "said outer shaft" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Double Patenting

17. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

18. Claims 4-11 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 3-9 respectively of U.S. Patent No. 6,214,036 to Letendre et al. in view of Johnson et al. (USPN 6,136,006). Letendre identically claims a delivery apparatus for a self-expanding stent, with the exception of one limitation. Letendre does not claim "shaft having a removable member on an exterior surface thereof adjacent to its proximal end, said removable member being sized such that it prevents said sheath from sliding along said shaft proximal to said member until it is removed therefrom" in the parent claim 1. Johnson teaches in the same field of endeavor, a delivery apparatus having a removable member (76) on shaft exterior surface (26), preventing sheath from sliding proximally, in order to prevent premature deployment of a stent (col.6, lines 61-67). It would have been obvious to one having ordinary skill in the art at the time the invention was made to

combine the Johnson's teaching of a removable member, with Letendre's delivery system, in order to provide a means to prevent premature stent deployment.

Claim Rejections - 35 USC § 102

19. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

20. Claims 1-3 are rejected under 35 U.S.C. 102(e) as being anticipated by Johnson et al. (USPN 6,136,006). Johnson discloses a delivery apparatus, which includes all limitations recited in the claims. Johnson discloses a delivery apparatus for a self-expanding stent (col.2, lines 11-12) comprising and outer sheath (exterior catheter, 18), an inner shaft (26), and a removable member (76) on shafts exterior surface. Johnson discloses a semi-cylindrical snap fitted removable member (col.7, lines 1-3) wherein the removable member (76) has an outer diameter larger than an outer shaft's (18) inner diameter (fig.1).

Claim Rejections - 35 USC § 103

21. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

22. Claims 4-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson et al. (USPN 6,136,006) in view of Rasmussen (USPN 5,324,304). Johnson discloses a delivery apparatus substantially as claimed. Referring to claim 4 and 6-11, Johnson discloses a delivery apparatus comprising an outer sheath (18), an inner shaft (26), a removable member (76) attached to shaft, and a self-expanding stent (66). Johnson does not disclose however, grooves on an inner shaft, legs attached to a stent, and legs having flanges. Rasmussen teaches a delivery system for a self-expanding member (abstract), wherein the self-expanding member has equally spaced legs (2), (19), extending distally and axially from stent member (fig.6, 7a), the legs having flanges (4) of various shapes (fig.6, 7a) that set completely into grooves (14) in an inner shaft (8, 10, 11, 18, 20) in order to retain self-expanding member at a compressed state and expand a vessel widely at a deployed state (col.1, lines 5-13; col.3, lines 50-55; col.4, lines 15-34). The applicant's specification has not deemed an I or T shape for flanges or grooves, as a critical feature therefore, Rasmussen's shapes are suitable and perform the same function of containing legs of a stent in an inner shaft upon delivery. It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine the teaching of Rasmussen's legs, flanges and grooves, with Johnson's stent delivery apparatus, in order to retain a self-expanding member at a compressed state and expand widely at a deployed state.

Referring to claim 5, Johnson discloses a superelastic nickel titanium stent.

Referring to claims 12-13, discloses a semi-cylindrical snap fitted removable member (col.7, lines 1-3) wherein the removable member (76) has an outer diameter larger than an outer shaft's (18) inner diameter (fig.1) in order to prevent premature deployment and axial movement of sheath.

Conclusion

23. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

USPN 5,797,952 to Klein discloses a delivery apparatus, wherein an inner shaft has grooves to accommodate a self-expanding nickel-titanium stent with end flanges.

USPN 6,221,096 B1 to Aiba et al. discloses a self-expanding stent having extension legs, wherein the stent is superelastic nickel-titanium.

USPN 6,290,728 B1 to Phelps et al. discloses a stent having legs with flanges for the purpose of widening and stabilizing a stent in a vessel.

Pub. No. US 2002/0007206 A1 to Bui discloses a stent delivery apparatus having an inner shaft, an outer shaft, and a removable member semicircular in shape, attached to inner shaft.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cheryl L. Miller whose telephone number is (703) 305-2812. The examiner can normally be reached on Monday through Friday from 7:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on (703) 308-2111. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3590.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Cheryl L. Miller
05/08/2002

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